(2) Name of the antibody or antibodies present as set forth in paragraph (d) of this section.

(3) Name, address (including ZIP Code), and license number of the manufacturer.

(4) Lot number, including sublot designations.

(5) Expiration date.

(6) Preservative used and its concentration.

(7) Number of containers, if more than one.

(8) Volume or equivalent volume for dried products when reconstituted, and precautions for adequate mixing when reconstituting.

(9) Recommended storage temperature in degrees Celsius.

(10) Source of the product if other than human serum or plasma.

(11) Reference to enclosed package insert.

(12) If a dried product, a statement indicating the period within which the product may be used after reconstitution.

(13) The statement: ''FOR IN VITRO DIAGNOSTIC USE.''

(14) The statement: ''MEETS FDA POTENCY REQUIREMENTS.''

(15) If human blood was used in manufacturing the product, the statement: ''CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.''

(16) A statement of an observable indication of an alteration of the product, e.g., turbidity, color change, precipitate, that may indicate possible deterioration of the product.

(c) *Package insert.* Each final container of Blood Grouping Reagent shall be accompanied by a package insert meeting the requirements of § 809.10. If two or more final containers requiring identical package inserts are placed in a single package, only one package insert per package is required.

(d) *Names of antibodies.*

BLOOD GROUP DESIGNATION FOR CONTAINER LABEL

Anti-A	Anti-Jk^{b}
Anti-A_1	Anti-Js^{a}
Anti-A, B	Anti-Js^{b}
Anti-A and B	Anti-K
Anti-B	Anti-k
Anti-C	Anti-Kp^{a}
Anti-C^{w}	Anti-Kp^{b}
Anti-c	Anti-Le^{a}
Anti-CD	Anti-Le^{b}
Anti-CDE	Anti-Lu^{a}
Anti-Co^{b}	Anti-Lu^{b}
Anti-D	Anti-M
Anti-DE	Anti-M^{g}
Anti-Di^{a}	Anti-N
Anti-E	Anti-P_1
Anti-e	Anti-S
Anti-Fy^{a}	Anti-s
Anti-Fy^{b}	Anti-U
Anti-I	Anti-Wr^{a}
Anti-Jk^{a}	Anti-Xg^{a}

[53 FR 12764, Apr. 19, 1988, as amended at 59 FR 23637, May 6, 1994; 67 FR 9587, Mar. 4, 2002]

Subpart D—Reagent Red Blood Cells

SOURCE: 52 FR 37450, Oct. 7, 1987, unless otherwise noted.

§ 660.30 Reagent Red Blood Cells.

(a) *Proper name and definition.* The proper name of the product shall be Reagent Red Blood Cells, which shall consist of a preparation of human red blood cells used to detect or identify human blood-group antibodies.

(b) *Source.* Reagent Red Blood Cells shall be prepared from human peripheral blood meeting the criteria of §§ 660.31 and 660.32 of this chapter, or from umbilical cord cells which shall be collected and prepared according to the manufacturer's biologics license application.

[52 FR 37450, Oct. 7, 1987, as amended at 64 FR 56454, Oct. 20, 1999]

§ 660.31 Suitability of the donor.

Donors of peripheral blood for Reagent Red Blood Cells shall meet the criteria for donor suitability under § 640.3 of this chapter, except that paragraphs (b)(5) and (6), (d), and (e) of § 640.3 shall not apply.

§ 660.32 Collection of source material.

Blood for Reagent Red Blood Cells from donors of peripheral blood shall